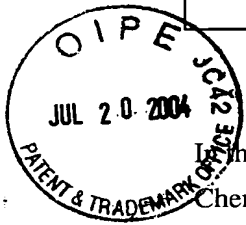


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Name: Linda S. Jernigan
Signature: *Linda S. Jernigan*



P&G Case 9188R&

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of :
Chen et al. : Confirmation No. 1244
Serial No. 10/810,358 : Group Art Unit 1616
Filed March 26, 2004 : Examiner

For Methods Of Determining Efficacy Of Treatments Of Diseases Of The Bowel

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. §§ 1.56, 1.97 and 1.98, record is being made on the attached Form PTO/SB08 of documents which the Patent Office may wish to consider in connection with examination of the above-identified patent application. It is respectfully requested that the cited documents be carefully considered by the Examiner and made of record in this case. As provided in §1.97(g), no representation is made or intended that a thorough art search was made. As provided in 37 C.F.R. §1.97(h), this Information Disclosure Statement does not constitute an admission of any kind, and specifically is not an admission that the documents listed on attached form PTO/SB08 are, or are considered to be, material to the patentability of the above-identified patent application, as defined in 37 C.F.R. §1.56(b).

1. ☐ **37 C.F.R. §1.97(b)(1) - U.S. Direct (use when filing IDS with nonprovisional patent application, or with Request for Continued Examination (RCE); or within 3 months of filing a nonprovisional patent application)**

This information disclosure statement, submitted under 37 C.F.R. §1.97(b)(1), is being filed with the patent application, with a Request for Continued Examination or within three months of the filing date of a national application. Therefore, no fee is believed to be due.

2. ☒ **37 C.F.R. §1.97(b)(3) - (use when filing IDS more than 3 months after filing a nonprovisional patent application, but prior to receipt of first Office Action)**

This information disclosure statement is being submitted under 37 C.F.R. §1.97(b)(3). Applicants have not received an Office Action on the merits in the present application. Therefore, no fee is believed to be due. However, in the event that this paper is crossing in the mail with a first Office Action on the merits, authorization is hereby given to charge the required fee pursuant to 37 C.F.R. §1.97(c) and 37 C.F.R. §1.17(p) to Deposit Account No. 16-2480 in the name of The Procter & Gamble Company. A duplicate of this letter (or a fee transmittal form) is enclosed to facilitate charging of the fee, if necessary.

3. ☐ **37 C.F.R. §1.97(b)(4) - (use when filing IDS prior to receipt of first Office Action after the filing of a Request for Continued Examination (RCE) under §1.114)**

This information disclosure statement is being submitted under 37 C.F.R. §1.97(b)(4). Applicants have not received a first Office Action after filing a Request For Continued Examination (RCE). Therefore, no fee is believed to be due. However, in the event that this paper is crossing in the mail with a first Office Action on the merits, authorization is hereby given to charge the required fee pursuant to 37 C.F.R. §1.97(c) and 37 C.F.R. §1.17(p) to Deposit Account No. 16-2480 in the name of The Procter & Gamble Company. A duplicate of this letter (or a fee transmittal form) is enclosed to facilitate charging of the fee, if necessary.

4. ☐ **37 C.F.R. §1.97(c) with fee payment - (use when filing IDS after receipt of first Office Action, and before receipt of Final Office Action, Notice of Allowance, or an action that otherwise closes prosecution)**

This information disclosure statement is being submitted under 37 C.F.R. §1.97(c). Applicant(s) have not received a final action under 37 C.F.R. §1.113, a notice of allowance under 37 C.F.R. §1.311, or an action that otherwise closes prosecution in the application (e.g., *Ex parte Quayle*) as of the date of this submission. Applicant(s) elect to pay the fee set forth in 37 C.F.R. §1.17(p). Please charge the fee set forth in 37 C.F.R. §1.17(p) to Deposit Account Number 16-2480 in the name of The Procter & Gamble Company. A duplicate copy of this letter (or a fee transmittal form) is enclosed to facilitate the charging of the fee.

5. ☐ **Information to be Considered with Continued Prosecution Application (CPA) Filing (use when filing IDS with a Continued Prosecution Application (CPA) for Design Case).** This information disclosure statement is being filed with a Continued Prosecution Application (CPA) filed under 37 C.F.R. 1.53(d).

ADDITIONAL ITEMS TO BE NOTED BY THE EXAMINER:

☐ (1) (For use with applications filed prior to or on June 30, 2003.) Copies of the cited documents are enclosed.

OR

☐ (2) (For use with applications filed after June 30, 2003.) In accordance with 37 C.F.R. §1.98(a)(2), Applicants are submitting copies of foreign patent documents and non-patent literature.

OR

☒ (3) All of the cited references were previously cited by or submitted to the USPTO in prior application Case No. 9188&, U.S. Patent Application Serial No. 10/404,512, filed April 1, 2003. Applicants claim priority to said application under 35 U.S.C. §120. Accordingly, copies of previously submitted references are not provided with this Statement, pursuant to 37 C.F.R. §1.98(d), but copies of the Information Disclosure Statement and PTOSB08 for U.S. Patent Application Serial No. 10/404,512 are enclosed for reference. It is respectfully requested that the cited documents be carefully considered by the Examiner and made of record in this case.

OR

☐ (4) Copies of all said documents, except Cite Numbers _____, were submitted and considered in parent application U.S. Patent Application Serial No. _____, filed _____. Applicant(s) claim priority to said application under 35 U.S.C. §120. Accordingly, copies of previously submitted references are not provided with this Statement, pursuant to 37 C.F.R. §1.98(d). Copies of references not previously submitted are enclosed. It is respectfully requested that the cited documents be carefully considered by the Examiner and made of record in this case.

☐ (5) Pursuant to 37 C.F.R. §1.98(c), a concise explanation of the relevance of each cited reference that is not in the English language is provided.

☐ (6) Applicants also respectfully request the Examiner to consider and make of record the co-pending applications listed on the attached page.



Additional information is attached.

Respectfully submitted,

By

Kelly L. McDow-Dunham

Attorney or Agent for Applicant(s)

Registration No. 43,787

(513) 622-0159

Date: July 15, 2004

Customer No. 27752

(IDS.doc) (Last Revised 05/27/04)



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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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SHEET 1 of 5

COMPLETE IF KNOWN

Application Number	10/404512
Confirmation Number	6502
Filing Date	April 1, 2003
First Named Inventor	Chen et al.
Group Art Unit	1616
Examiner Name	
Attorney Docket Number	9188&

U. S. PATENT DOCUMENTS

EXAMINER INITIALS*	Cite No. ¹	DOCUMENT NUMBER		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
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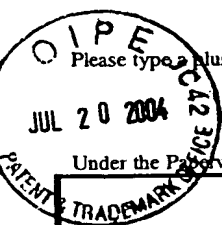
FOREIGN PATENT DOCUMENTS

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		Country Code ³	Number ⁴	Kind Code ⁵ (if known)				
		EP	0,508,701B1		10-14-1992	Quest International B.V.		
		EP	0,862,863B1		09-09-1998	Societe Des Products Nestle S.A.		
		EP	1,312,667A1		05-21-03	Wakamoto Pharmaceutical Co., LTD		
		W0	00/41707A1		07-20-2000	Enterprise Ireland		
		W0	00/42168A2		07-20-2000	Enterprise Ireland		
		W0	02/083879A2		10-24-2002	Alimentary Health LTD.		
		W0	03/010297A1		02-06-2003	Alimentary Health LTD.		
		W0	03/010298A1		02-06-2003	Alimentary Health LTD.		
		W0	03/010299A1		02-06-2003	Alimentary Health LTD.		
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First Named Inventor	Chen et al.
Group Art Unit	1616
Examiner Name	
Attorney Docket Number	9188&

SHEET 2 of 5

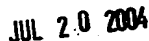
NON PATENT LITERATURE DOCUMENTS

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		AGA, Abstracts, Gastroenterology Vol. 116 No. 4	
		HENRY J. BINDER, M.D., "Genes, Bacteria and T Cells: Ingredients for Inflammatory Bowel Disease", Selected Summaries, Gastroenterology 1998; 115: 1695-1600, Vol. 115, No. 6	
		O'MAHONY ET AL., "Probiotic Bacteria and the Human Immune System", Dept. Microbiology and Medicine, National Food Biotechnology Centre, University College Cork & Dept. Surgery, Mercy Hospital, Cork Ireland	
		O'HALLORAN ET AL., "Adhesion of Potential Probiotic Bacteria to Human Epithelial Cell Lines", Departments of Microbiology and Medicine, University College, Mercy Hospital, Cork, Ireland, Dept. of Surgery, Mercy Hospital, Cork, Ireland	
		STALLMACH ET AL., "Induction and Modulation of Gastrointestinal Inflammation", Trends Immunology Today, October 1998, Vol. 19 No. 10 pages 438-441	
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SHEET 3 of 5

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Application Number	10/404512
Confirmation Number	6502
Filing Date	April 1, 2003
First Named Inventor	Chen et al.
Group Art Unit	1616
Examiner Name	
Attorney Docket Number	9188&

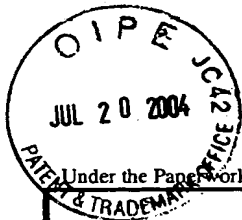
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		O'MAHONY ET AL., "Probiotic Bacteria and Pathogenic Bacteria Elicit Differential Cytokine Responses From Dendritic Cells", XP-001097379	
		CHARTERIS ET AL., "Antibiotic Susceptibility of Potentially Probiotic Bifidobacterium Isolates From the Human Gastrointestinal Tract", Letters in Applied Microbiology 1998, 26, 333-337	
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		GROUX ET AL., "Regulatory T Cells and Inflammatory Bowel Disease", Viewpoint Immunology Today October 1999	
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INFORMATION DISCLOSURE
STATEMENT BY APPLICANT

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SHEET 4 of 5

Application Number	10/404512
Confirmation Number	6502
Filing Date	April 1, 2003
First Named Inventor	Chen et al.
Group Art Unit	1616
Examiner Name	
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		ARANDA ET AL., "Analysis of Intestinal Lymphocytes in Mouse Colitis Medicated by Transfer of CD4+, CD45RB high T Cells to SCID Recipients", 1997, The American Association of Immunologists	
		BRANDTZAEG ET AL., "Immunopathology of Human Inflammatory Bowel Disease", Springer Seminars in Immunopathology (1997) 18: 555-589	
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		STROBER ET AL., "Reciprocal IFN-gamma and TGF-Beta Responses Regulate the Occurrence of Mucosal Inflammation", Immunol Today. 1997 Feb;18(2):61-4	
		BARBARA G. ET AL., "A Role for Inflammation in Irritable Bowel Syndrome, Gut 51:i41-i44	
		CHADWICK ET AL., "Activation of the Mucosal Immune System in Irritable Bowel Syndrome", Gastroenterology (2002) 122:1778-83	
		ANAND ET AL., "Cytokines and Inflammatory Bowel Disease", Tropical Gastroenterology. 1999; 20(3):97-106	

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		GASCHE ET AL., "IL-10 Secretion and Sensitivity in Normal Human Intestine and Inflammatory Bowel Disease", Journal of Clinical Immunology Vol. 20, No. 5, 2000	
		HOMMES ET AL., "Anti- and Proinflammatory Cytokines in the Pathogenesis of Tissue Damage in Crohn's Disease", 2000 Lippincott Williams and Wilkins 1363-1950	
		MCKAY ET AL., "Review article: In Vitro Models in Inflammatory Bowel Disease", Aliment Pharmacol Ther 1997; 11 (Suppl. 3): 70-80	
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		POWRIE ET AL., "Inhibition of Th1 Responses Prevents Inflammatory Bowel Disease in Scid Mice Reconstituted with CD45Rbhi CD4+ T Cells, Immunity Vol. 1, 553-562, October, 1994	
		VAN DAMME ET AL., "The Proportion of Th1 Cells, Which Prevail in Gut Mucosa, is Decreased in Inflammatory Bowel Syndrome", Clin Exp Immunol 2001; 125:383-390	
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